



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Wednesday, January 30, 2008

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. Nos.: 74986-4 & 74986-5
DP Barcode: 344754/344824

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

A handwritten signature in black ink, appearing to read "Michele E. Wingfield", written over the typed name and title.

To: Emily Mitchell, PM 32/ Wanda Henson
Regulatory Management Branch
Antimicrobials Division (7510C)

Applicant: Selective Micro Technologies, LLC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Sodium chlorite	30.5
<u>Other Ingredient(s):</u>	<u>69.5</u>
Total:	100.0

- 1) **BACKGROUND:** Selective Micro Technologies, LLC., has submitted a follow-up to previous acute toxicity submissions for Registration Number 74986-5.

The Chemistry and Toxicology Team (CTT) conducted an acute toxicology review of 74986-5 on 5/7/2007. The results of that review were:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	463908-01	III	Cited
Acute Dermal Toxicity	463908-02	IV	Cited
Acute Inhalation Toxicity		?	Data Gap
Primary Eye Irritation	457782-06	I	Cited
Primary Skin Irritation	463908-03	I	Acceptable
Dermal Sensitization	465771-01	Nonsensitizer	Cited

CTT received an email from H. Lindsey Parris of Selective Micro Technologies. This communication addresses the acute toxicity requirements of Registration Numbers 74986-4 and -5. One of the matters noted is that Selective "... did request a waiver for the acute dermal toxicity, again with a single request applying to both 74986-4 and 74986-5 products, because of bridging rationale." As frequently happens with Agency personnel and registrants, Selective may be confusing waivers and bridging requests.

Also addressed in this email, the registrant cites an acute inhalation toxicity study that was previously submitted to support the registration of 74986-4 and -5. That 2003 report is assigned Product Safety Labs study number, PSL 14125.

- 2) **RECOMMENDATIONS:** PSB findings are:

- a) There is no need for a waiver of the acute dermal toxicity study for this product. According to Agency files, CTT previously accepted an acute dermal toxicity study for this product and assigned that study toxicity category IV. As the undiluted product is assigned toxicity category IV for acute dermal toxicity, this category will also be assigned to the use-dilutions of this product.
- b) The acute inhalation toxicity study is assigned toxicity category IV.

The acute toxicity profile for Registration Number 74986-5 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	463908-01	III	Cited
Acute Dermal Toxicity	463908-02	IV	Cited
Acute Inhalation Toxicity		IV	Cited
Primary Eye Irritation	457782-06	I	Cited
Primary Skin Irritation	463908-03	I	Acceptable
Dermal Sensitization	465771-01	Nonsensitizer	Cited

The acute toxicity profile for the use-dilution of 74986-5 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity		IV	Cited
Acute Dermal Toxicity		IV	Cited
Acute Inhalation Toxicity		IV	Data Gap
Primary Eye Irritation		III	Cited
Primary Skin Irritation		III	Acceptable
Dermal Sensitization		Nonsensitizer	Cited

3) LABELING:

a) The Signal Word is:

- i) "DANGER" for the undiluted product.
- ii) "Caution" for the use dilutions.

b) Precautionary Statements:

- i) Undiluted product:

The precautionary statements should be amended to include the following:

Do not get in eyes or on clothing.

ii) Diluted product:

The precautionary statements should be amended to include the following:

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.